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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,967	02/15/2002	William E. Rich	016866-005710US	1477
20350 7590 12/22/2006 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER CLOW, LORI A	
			ART UNIT 1631	PAPER NUMBER

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/22/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/076,967	RICH ET AL.	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 55-66 and 68-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 55-66 and 68-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/14/06</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicants' response, filed 28 September 2006, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 55-66 and 68-81 are currently pending. Claims 1-54 and 67 have been cancelled.

Information Disclosure Statement

The Information Disclosure Statement filed 14 November 2006 has been considered. A signed copy of PTO Form 1449 is included with this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 55-66 and 68-81 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection and is necessitated by amendment to the claims.

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Claim 55, as amended, recites, “a method of comparing the correlation between gene and protein expression in two or more biological samples”. Applicant is reminded that “an Applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Applicant, however, has not pointed to support for the newly recited limitation of “**comparing the correlation**” and none is apparent in the specification as originally filed. Rather, the specification describes that the “present invention provides methods for **correlating gene expression with protein expression**” (page 3, lines 23-24). Further, “the present invention provides methods that combine RNA and protein expression profiling, to identify genes and the proteins expressed in cells under different conditions, e.g., at different times in the cell cycle, under varying environmental conditions (such as ion influx or efflux; exposure to a toxin; drug; ligand; e.g., a hormone, a cytokine, or a chemokine; or a pathogen such as a virus, bacteria, protozoa, or fungus), under varying pathological conditions, such as cancer, at different times during maturation and differentiation, at different times during development of the organism, during responses such as inflammation, in different tissue types or organs, in different pathological conditions such as cancer or autoimmune disease, between individuals with different phenotypic traits, e.g., responders vs. non-responders to a particular pharmaceutical drug, etc. The methods of the present invention, e.g., allow one of skill in the art to identify a list of candidate genes expressed in a cell or biological sample, and then to further identify a subset of proteins of interest encoded by the genes of interest using the methods of the invention. The methods of the invention are also useful for combining information related to

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mRNA expression to expression and function of the protein encoded by the mRNA. The invention, therefore, **provides a method of correlating gene and protein expression in a cell**" (page 4, lines 21-24 to page 5, lines 1-3).

The concept of "comparing a correlation" is not the same as correlating one expression level (gene) with another expression (protein) level. No correlation between the gene and protein expression is even established within the method steps of the claim. The claims, therefore, contains NEW MATTER.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 55-66 and 68-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 55, as amended, recites, "thereby comparing the correlation between gene and protein expression in two or more biological sample". This claim limitation is unclear because no actual "correlation of gene and protein expression" has been performed within the steps of the claim. Therefore, it is unclear what correlations are being compared. The only correlation is that of a polypeptide that has a mass that correlates to the predicted mass. However, this is not the same as a correlation between gene and protein expression. Does Applicant intend that the correlation of gene and protein expression be indicated by a predicted mass that is the same as a mass in generated the protein profile? Clarification is requested.

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Claim 55, as amended, recites, “determining the nucleotide sequence of **an** mRNA in each gene expression profile” in step (c). In step (d) the amino acid sequence of that one mRNA is predicted. In step (e) the mass of the one polypeptide is predicted and in step (g) the presence or absence of one polypeptide is determined by correlating the mass to the predicted mass.

The claim is unclear because if the protein is present in only one sample, or in no samples (as is also recited in the claim; i.e. “absence”), then the steps of the claim have only correlated expression in one sample (or none). There has not necessarily been a correlation of the one gene with expression of a protein in two or more samples, as is recited in the claim. Further, the steps have not correlated any and all genes to any and all expressed proteins, which is an embodiment encompassed by the language of the claims. Lastly, the steps have not correlated expression of a plurality of genes to one or more proteins or one gene to a plurality of proteins, also encompassed by the language of the claims. Clarification is requested through clearer claim language.

Conclusion

No claims are allowed.

The outstanding rejection under 35 USC 101 (non-statutory subject matter) has been withdrawn in view of Applicant’s arguments. Further, the step of mass spectrometry is interpreted in the claim to constitute a physical transformation and therefore the claim is statutory.

Applicant has corrected the outstanding Objections to the claims.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of

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the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

December 19, 2006

Lori A. Clow, Ph.D.

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Lori A. Clow
Patent Examiner